K 071363

FEB 12 2008

510(k) Summary of Safety and Effectiveness Information

Regulatory Authority:	**Safe Medical Devices Act of 1990, 21 CFR 807.92**
Company:	**Biolase Technology, Inc. 4 Cromwell Irvine, CA 92618**
Contact:	**Ms. Ioana M. Rizoiu Biolase Technology, Inc. 4 Cromwell Irvine, CA 92618 Tel: (949) 226-8144 Fax: (949) 273-6680**
Trade Name:	***Waterlase® and Waterlase® MD***
Common Name:	**Er,Cr:YSGG laser**
Classification Name:	**Surgical laser instrument**
Classification Code:	**79 GEX, MXF, DZI a Class II device**

Equivalent Devices:

Biolase Technology, Inc.	***Waterlase®***
Dentsply Intl, Inc.	***EndoPure™ Root Canal Cleanser***
Dentsply Intl, Inc.	***BioPure® MTAD® Root Canal Cleanser***

Device Description:

The ***Waterlase®/Waterlase®MD*** dental laser system is a device used to perform a variety of dental soft and hard tissue indications. For hard tissue procedures the ***Waterlase®/Waterlase®MD*** uses the Erbium, Chromium: Yttrium, Scandium, Gallium Garnet (Er,Cr:YSGG) laser in combination with advanced water atomization spray technology to cut, remove, shave, contour, roughen and etch tissues. Soft tissue procedures are performed using a different mode of operation where direct Er,Cr:YSGG laser energy is applied to incise, excise or ablate these tissues. For soft tissue procedures the water spray is applied for hydration, cooling or to keep tissues and the field of view clean. For hard tissue applications the spray is part of the tissue removing process as well as hydration, cooling and keeping tissues and field of view clean.

A flexible fiberoptic terminated into the handpiece delivers the ***Waterlase®/Waterlase®MD*** laser energy to the end fiber tip and target. A visible aiming light emitted from the handpiece's distal end pinpoints the area of treatment.

Three fiber optic ports provide illumination from the handpiece to the tissue site in addition to the center beam emitting source. In both hard and soft tissue applications the power output, pulse duration, repetition rate (frequency) and air and water flow rates are adjustable to specific user requirements. The spot size and spot geometry can also be varied by changing tips which include different diameters and end configurations.

Indications for Use:

Root Canal Disinfection

Laser root canal disinfection after endodontic instrumentation

Contraindications:

All clinical procedures performed with ***Waterlase®/Waterlase®MD*** must be subject to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions, which might contraindicate a local procedure. Such conditions may include, but are not limited to, allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea or an immune system deficiency. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

Substantial Equivalence:

The purpose of the 510(k) is to expand the ***Waterlase®***, and ***Waterlase®MD*** indications for use to include root canal disinfection, an indication that has already been cleared by the FDA for equivalent medical devices. The ***Waterlase®***, and ***Waterlase®MD*** have already been cleared by the FDA for indications which relate to root canal procedures and surgical endodontic procedures related to root end amputation. Other indications cleared for this device include cavity preparations class I, II, III, IV and V, cutting, shaving, contouring and resection of osseous tissue, osteotomy, hard tissue roughening or etching, enameloplasty, soft tissue procedures and periodontal procedures related to surgery and the periodontal pocket. The ***Waterlase®***, and ***Waterlase®MD*** indications enumerated above have been cleared by the FDA as part of the 510(k) submissions K031140, K013908, K030523, K022803, K011041, K012511, K990908, and K990219. For the indication on root canal disinfection requested with this submission, the ***Waterlase®***, and ***Waterlase®MD*** are equivalent to the following products: BIOPURE MTAD Root Canal Cleanser K053167, and EndoPure Root Canal Cleanser K032361. Comparison between ***Waterlase®***, and ***Waterlase®MD*** and the predicate devices is included in Table 1. Based on the comparison, the ***Waterlase®***, and ***Waterlase®MD*** are substantially equivalent in relation to previous clearances.

Equivalency was further substantiated through performance data, including in-vitro evaluation of anti-microbial efficacy of the

Er,Cr:YSGG (***Waterlase®***) and the evaluation of the temperature rise which related to the safety of these devices during root canal disinfection. Copies of the study reports are included under section 8, titled Performance Data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2008

BIOLASE Technology, Inc.
% Ioana Rizoiu
VP, Clinical Research &
Development
4 Cromwell
Irvine, California 92618

Re: K071363
Trade/Device Name: Waterlase® and Waterlase® MD
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX, MXF
Dated: January 4, 2008
Received: January 8, 2008

Dear Ioana Rizoiu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071363

Device (Trade) Name: Waterlase® and Waterlase® MD

Indications for Use:

Root Canal Disinfection

- Laser root canal disinfection after endodontic instrumentation

Prescription Use X AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sept 04 2007

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071363